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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/997,850 | 11/29/2001 | Brian P. Brockway | 349.033US3 | 6258 |

21186 7590 01/31/2005

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| EXAMINER | |
|---|---|
| NASSER, ROBERT L | |
| **ART UNIT** | **PAPER NUMBER** |
| 3736 | |

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/997,850 | BROCKWAY ET AL. | |
| | Examiner | Art Unit | |
| | Robert L. Nasser | 3736 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *57-64,66-69,72-76,78-81,83-85,87 and 89-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-64, 66-69, 72-76, 78-81, 83-85, 87, 89-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/28/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/28/2004 has been entered.

Applicant has requested a copy of the IDS filed 4/14/2004. The examiner notes that no such IDS has been received.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 57-64, 66-69, 72-76, 78-81, 83-85, 87 and 89-123 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6033366. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are merely differently worded versions of the patented claims and, as such, are covered by the patented claims. As to the length of the current catheter, it is the examiner's

position that since both catheters are for the same purpose, it would have been obvious to make the catheters the same length.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 57, 59, 61-63 and 105-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al 3893451 in view of Brockway et al 4,846,191. Durand et al has a pressure transmitting catheter having a lumen entirely filled with a pressure transmitting liquid. The transmitting catheter of Durand et al includes a first layer of material 1 made of a plastic surrounding the lumen, and a second material 4 of metal, having a differing hardness surrounding the first layer of material. Durand teaches that one end of the catheter connects to a pressure measuring catheter via connector 2, and that the second end connects to an instrument for measuring pressure. It does not have an implantable monitor housing the transducer and the signal processing equipment. However, Brockway teaches using such an implantable housing with a wireless connection to an external monitor, for several reasons, including to avoid the risk on infection that catheter passing through the skin impose (see background section in general, with specific reference to the discussion in the first paragraph of column 2). Hence, it would have been obvious to modify Durand to use such an implantable transducer housing, so as to overcome the problems with catheters discussed in Brockway. With respect to claims 59 and 64, Brockway teaches an alternative

pressure transmitting medium comprised of a gel and a fluid combination. Hence, it would have been obvious to modify Durand et al to use this medium, as it is merely the substitution of one known medium for another. With respect to claims 61, 62, 67, and 68, the combined device teaches wirelessly transmitting the data to a remote location away from the patient. With respect to claim 63, the device can be used to measure the pressures listed. In addition, with respect to claims 105-110, applicant has not stated that the type of material used for the two layers of the durometer solves a stated problem is for a particular purpose. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for layers 3 and 4, particularly since it appears that any material would function equally as well as any other.

Claims 58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view Brockway et al 4846191, as applied to claims 57, 59, 61-63, and 105-110 above, further in view of Iwata et al 6019728. Durand et al uses a pressure transmitting liquid as the pressure transmitting medium. Iwata et al uses a gel as the pressure transmitting medium to fill the entire catheter. From this teaching, it would have been obvious to modify the above combination to use a gel, to simplify the overall design.

Claims 64 and 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view Brockway et al 4846191 and Iwata et al 6019728. In addition to the features of the Durand/Brockway combination discussed above, Durand et al uses a pressure transmitting liquid as the pressure transmitting medium. Iwata et al uses a gel as the pressure transmitting medium to fill the entire catheter. From this teaching, it would have been obvious to modify the above combination to use a gel, to simplify the overall design.

Claims 69, 72, 99-101, and 111-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view Pohndorf et al 5,353,800. Durand teaches that the pressure transmitting catheter may connect to a measuring instrument having a transducer. Pohndorf et al shows a device where the pressure transmitting catheter connects to a transducer, which in turn has a wire extending through a catheter to an implanted medical device, which includes a signal processing device. Such an arrangement allows the wires to be protected from the external environment and allows for improved measurement, as the transducer is located close to the measurement site. Hence, it would have been obvious to modify Durand to use such a configuration, as it is merely the use of a well known configuration in the art and to improve measurement accuracy. Claims 72 and 99-101 are rejected in that the needle of Pohndorf, e.g. the PTC, is one inch long, which is in the claims range and is approximately 1.5 cm. In addition, with respect to claims 111-113, applicant has not stated that the type of material used for the two layers of the durometer solves a stated problem is for a particular purpose. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for layers 3 and 4, particularly since it appears that any material would function equally as well as any other.

Claims 73, 74, and 78-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand in view of Pohndorf et al as applied to claims 69, 72, 99-101, and 111-113 above, and further in view of Brockway 4846191. With respect to claims 73 and 74, Brockway teaches an alternative pressure transmitting medium comprised of a gel and a fluid combination. Hence, it would have been obvious to modify the Durand/Pohndorf combination to use this medium, as it is merely the substitution of one known medium for another. In addition, with respect to claims 78 and 79, it would have been obvious to modify the above combination locate the transducer in an internal

housing and to transmit the data out of the body, for the reasons discussed in the rejection to claim 57 above. With respect to claim 80, the Durand/Pohndorf combination teaches that it can use an implantable medical device remote from the transducer.

Claims 81, 83, 84, 96-98, and 114-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view of Brockway et al 4846191 and Iwata 6019728. Durand et al uses a liquid as the pressure transmitting medium, in addition to the features of the taught by Durand and Brockway above, Iwata et al uses a gel as the pressure transmitting medium to fill the entire catheter. From this teaching, it would have been obvious to modify the above combination to use a gel, to simplify the overall design. In addition, with respect to claims 114-116, applicant has not stated that the type of material used for the two layers of the durometer solves a stated problem is for a particular purpose. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for layers 3 and 4, particularly since it appears that any material would function equally as well as any other.

Claims 85, 87, 89, 90, and 102-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view of Brockway and Iwata, as applied to claims 81, 83, 84, 96-98 and 114-116 above, further in view of Pohndorf et al. Durand teaches that the pressure transmitting catheter may connect to a measuring instrument of a transducer. Pohndorf et al shows a device where the pressure transmitting catheter connects to a transducer, which in turn has a wire extending through a catheter to an implanted medical device, which includes a signal processing device. Such an arrangement allows the wires to be protected from the external environment. Hence, it would have been obvious to modify the above combination to use such a configuration, as it is merely the use of a well known configuration in the art. With respect to claims 87 and 102-104, the needle of Pohndorf, e.g. the PTC, is one inch long, which is in the

claims range and is approximately 1.5 cm. As such, it would have been obvious to make the device of the combination of the same size, as it is merely the substitution of one known catheter size for another.

Claim 75 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 91-95 and 117-123 would be allowable if the double patenting rejection were overcome.

Claims 75 and 91-95 define over the art of record in that none of the art has the slidable plug, as claimed.

Claims 117-123 define over the art of record in that none of the art teaches a pressure transmission catheter with a pressure transmitting medium therein, where the catheter has an interior layer surrounding the lumen that is harder than an exterior layer surrounding the lumen.

Applicant's arguments filed 10/28/2004 have been fully considered but they are not persuasive.

Applicant has asserted that if Durand were modified to include an implanted housing, there would be no reason to use the reduced diameter section and hence the two layers of material in Durand to eliminate resonant frequencies. The examiner notes that Durand teaches that he second layer is necessary to eliminate resonant frequencies. However, it is the examiner's position that Durand does not teach that the resonant frequencies area problem because of the catheter length. It seems that a shorter catheter would still have resonant frequency problems. If applicant has evidence that suggests that short catheters have no issues with resonant frequencies or

that the frequency are reduced to negligible levels in a shorter catheter, the examiner would appreciate it being made of record and the issue will be revisited.

With respect to claim 64, applicant has asserted that Brockway teaches away from filing the lumen entirely with a gel. First, the examiner notes that teaching away means that there is a specific teaching that a lumen filled entirely with a gel cannot be used. This is not present in Brockway. Second, the issue is whether Durand teaches away, as it is Durand and not Brockway that is being modified.

Applicant has requested evidence to support the assertion of obviousness with respect to claim 58, 60 and 64. The examiner does not understand this request. The examiner has demonstrated, for example, that one pressure transmission catheter uses a liquid transmission medium and one uses a gel, in the case of Iwata, or uses a gel and liquid combination, in the case of Brockway. As such, the art demonstrates that these mediums are equivalents in that the perform the same function. It is the examiner's position that the record has clear evidence to support the combination.

With respect to claim 69, applicant has stated that there is no teaching or suggestion in Pohndorf to eliminate resonant frequencies in its device. It is the examiner's position that the Federal Circuit has made it abundantly clear that a reference is good for all it teaches. In addition, there is no requirement in the patent laws that references must be identical to be combinable. In addition, the examiner further notes that the Federal Circuit has made it clear that there is no requirement that the suggestion to combine come from the text of the references. It is the examiner's

position that in the current situation, when view as a whole, Durand and Pohndorf suggest the modification.

In addition, applicant has asserted that the Durand/Pohndorf combination does not suggest modifying the tube of Durand to make it implantable. It is the examiner's position that the tube is already implantable.

The arguments with respect to claim 81 have been addressed above.

Applicant has further asserted that the examiner has not established a prima facie case of obviousness for claim 96. The examiner disagrees, noting that the reasons for the modification were presented in the rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
January 10, 2004

ROBERT L. NASSER
PRIMARY EXAMINER